CHF QUERI News

The VA Chronic Heart Failure Quality Enhancement Research Initiative, Feb. 2000

The mission of the CHF QUERI is to create measurable, rapid, and sustainable improvements in the quality of care and health outcomes of veterans with heart failure.

Notice: Safety of Spironolactone for Heart Failure Patients

- In 1999, the Randomized Aldactone Evaluation Study (RALES) reported that blockade of aldosterone receptors by spironolactone, in addition to standard pharmacological therapy, substantially reduced the risk of both morbidity and death among patients with severe heart failure, with a minimal incidence of serious hyperkalemia (Pitt B et al., NEJM 1999;341(10):709-17).
- Since this report was issued, there have been sporadic cases of serious hyperkalemia associated with the use of spironolactone in patients with heart failure. A few of these patients have required temporary pacemaker insertion.
- The CHF QUERI Coordinating Center is sending this notice to remind VA clinicians about the necessary patient criteria, dosing requirements, laboratory follow-up, and medication adjustments that were used to ensure patient safety in RALES.

Inclusion Criteria for Spironolactone Use in RALES

- Left ventricular systolic dysfunction with chronic heart failure of New York Heart Association (NYHA) functional class III or IV
- Other potassium-sparing diuretics were not permitted
- Oral potassium supplements were not recommended unless hypokalemia (defined as a serum potassium concentration of less than 3.5 mmol per liter) develops

Exclusion Criteria for Spironolactone Use in RALES

- Serum potassium concentration of more than 5.0 mmol per liter or renal insufficiency with a serum creatinine concentration of more than 2.5 mg per deciliter (221 μmol per liter)

Dose of Spironolactone

- 25 mg of spironolactone once daily
- If heart failure progresses, the dose of spironolactone may be increased to 50 mg once daily. If hyperkalemia develops, the dose should be decreased to 25 mg every other day. However, spironolactone should be withheld in the event of serious hyperkalemia or a serum creatinine concentration of more than 4.0 mg per deciliter.

Recommended Laboratory Follow-Up

- Serum potassium should be measured every 4 weeks for the first 12 weeks, then every 3 months for up to 1 year and every 6 months thereafter.
- In patients for whom the dose is increased to 50 mg, serum potassium should be measured one week after the dose increase, and then follow the above schedule.

VA QUERI
Quality Enhancement Research Initiative

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